



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

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NOV 25 2002

Mr. Steve Lee  
V. P. Technical Affairs  
Technical Sourcing International, Inc.  
201 West Main  
Suite 101  
Missoula, Montana 59802-4326

Dear Mr. Lee:

This is in response to your letter of November 4, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). In your letter, you notified us about a claim you intend to use for your dietary supplement **Promilin™**.

The product **Promilin™** uses the claims "Supports healthy blood sugar metabolism," "Helps balances blood sugar," "Enhances sensitivity of insulin response" and "Promotes glucose-induced insulin release." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to your claims about control of blood sugar level and insulin sensitivity; that is, a claim that does not establish that the claim is about blood sugar or insulin sensitivity that is already within normal limits implies that the product is intended to treat elevated blood sugar or diabetes, which is a disease.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases, namely diabetes or other disorders of blood sugar regulation. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug

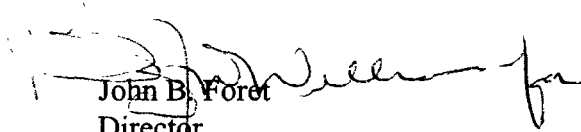
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within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855. Please contact us if you require further assistance.

Sincerely yours,



John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Seattle District Compliance, HFR-PA340



**TECHNICAL  
SOURCING**  
International, Inc

NOV 14 2002

November 4, 2002

Attn: Christine L. Taylor, Ph.D.  
Director  
Office of Nutritional Products, Labeling, and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C Street SW  
Washington, D.C. 20204

Dear Dr. Taylor,

Pursuant to section 6 of the Dietary Supplement Health and Education Act, Technical Sourcing International, Inc. wishes to notify the U.S. Food and Drug Administration that it has, within the past 30 days, commenced marketing a dietary supplement. The supplement, a standardized extract of fenugreek seed called Promilin™, bears the following structure/function claims:

- Promotes glucose-induced insulin release
- Supports healthy blood sugar metabolism
- Helps balances blood sugar
- Enhances sensitivity of insulin response
- Helps promote healthy muscle mass
- Aids in the transport of glucose to skeletal muscle
- Aids in muscle growth and recovery
- Reduces body fat potential

We have the claim substantiation on file. The proper disclaimer accompanies the claims and is displayed prominently. We believe the above claims are substantiated, truthful, and not misleading.

Sincerely,

Steve Lee, V.P. Technical Affairs

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